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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/782,014 | 02/19/2004 | Selena Chan | 42P14581 | 4300 |

7590 05/29/2009

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| EXAMINER | |
|---|---|
| SMITH, CAROLYN L | |
| ART UNIT | PAPER NUMBER |
| 1631 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 05/29/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/782,014 | CHAN ET AL. | |
| | Examiner | Art Unit | |
| | Carolyn Smith | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *2/25/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4,6 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's amendments and remarks, filed 2/25/09, are acknowledged. Cancelled claims 5, 7, and 13-29 are acknowledged.

Applicant's arguments, filed 2/25/09, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-4, 6, and 8-12 are herein under examination.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Chan (US 2002/0119455 A1). This rejection is maintained and reiterated for reasons of record.

Chan discloses a method of sequencing a polymer (abstract, 0025) by dividing a polymer sample into a number of polymer subsamples wherein there is a polymer subsample created for each monomer present in the polymer sample wherein only one monomer type in each subsample is labeled and wherein both labeled and unlabeled instances of the one monomer type are incorporated (0036, 0264, 0265, 0278), sequentially separating each monomer from the polymer subsample (Figure 3, 0131, 0147, 0006, 0015, 0200, claim 122), detecting labels of each

separated labeled monomer as a function of time (Figures 2, 3, 0205, 0271, 0274, 0277, 0313), constructing a time map for each monomer in each polymer subsample (Figure 3; 0277; claims 12, 18), and assembling the time maps into a polymer sequence (Figure 3, 0271, 0277, 0025), as stated in instant claim 1. Chan discloses the polymer is a nucleic acid, the monomer is a nucleotide, and the number of polymer samples and different monomer types is four (0277), as stated in instant claim 2. Chan discloses subsample size of 100,000 (Figure 1, 0312), as stated in instant claim 3. Chan discloses the labels are bulky groups (0036, claims 9, 125), as stated in instant claim 4. Chan discloses attaching the polymer subsample to a surface (0207, 0033, 0101, 0206), as stated in instant claim 6. Chan discloses the polymer is a nucleic acid and using exonuclease sequencing (0006, 0015, 0200), as stated in instant claim 8. Chan discloses detecting time between labels with a time-gated detection optical photodetector device (0213-0216, 0224, 0238-0241, 0088), as stated in instant claims 9, 10. Chan discloses constructing monomer time maps of each polymer subsamples comprising analyzing the measured time by overlapping data analysis and frequency analysis to construct the time maps as well as assembling maps comprising minimum non-overlapping data analysis (Figure 3, 0025, 0131, 0278, 0073), as stated in instant claims 11, 12. Chan discloses a method of sequencing a polymer (abstract, 0025) by dividing a polymer sample into a number of polymer subsamples wherein there is a polymer subsample created for each monomer present in the polymer sample wherein only one monomer type in each subsample is labeled and wherein both labeled and unlabeled instances of the one monomer type are incorporated (0036, 0264, 0265, 0278), moving an intact polymer across a detector (0033, 0205, 0271), measuring time between labeled monomers (0034, 0213), constructing a time map for each detected labeled monomer (Figure 3),

repeating steps (Figure 3; 0277; claims 12, 18), and assembling the time maps into a polymer sequence (Figure 3, 0271, 0277, 0025). Chan discloses at least one end of each nucleic acid is attached to a distinguishable label (0277).

Thus, Chan anticipates the instant invention.

Applicant argues Chan fails to disclose a sequencing method wherein "sequentially separating each monomer from the polymer subsample" and detection of the separated monomer ("detecting the labels of each separated labeled monomer as a function of time") occurs. This statement is found unpersuasive as Chan discloses sequentially separating each monomer from the polymer subsample (Figure 3, 0131, 0147, 0006, 0015, 0200, claim 122), detecting labels of each separated labeled monomer as a function of time (Figures 2, 3, 0205, 0271, 0274, 0277, 0313). Applicant argues the claims of the present application are directed to sequencing methods in which monomers of a polymer subsample are detached and detected while Chan teaches that the polymer remains intact for the analysis. Applicant further argues Chan describes detecting the labels of a polymer, for example, Chan states, "[t]he point where the polymer passes the localized region of agent is the interaction station. As each labeled unit of the polymer passes by the agent a detectable signal is generated." (Chan, page 19, paragraph [0206].) This statement is found unpersuasive as instant claim 1 recites "sequentially separating each monomer", not detaching each monomer. It is noted that separation in its broadest reasonable interpretation may be a visual separation, not necessarily a physical separation. Also, Chan discloses units (i.e. monomers) are sequentially exposed to the agent which "is meant in general separated from one another in time" (0147). Applicant argues Chan further teaches away from the desirability of

separating monomers (or "exonuclease sequencing"), with statements such as "[i]n practice, exonuclease sequencing has encountered many difficulties in each of the steps. The labeling step requires that all four bases in the DNA be tagged with different fluorophores. Sterically, this is extremely unfavorable... Furthermore, difficult optical trapping is needed to suspend DNA molecules in a flowing stream. The step is time intensive and requires considerable expertise. Lastly, single molecules of fluorophore need to be detected with high efficiency." (Chan, page 2, paragraph [0016].) This statement is found unpersuasive as while it may be time intensive and require expertise, it has been done before. Chan discloses exonuclease sequencing has the theoretical capability of long length reads (0019) and mentions fluorometric cleavage assays (0200). In addition, "separating" monomers does not necessarily involve using exonuclease sequencing, as described above (i.e. visual separation). Applicant argues since not all the elements of the claims can be found in the prior art invention of Chan, Chan does not anticipate the present invention. This statement is found unpersuasive as Chan discloses all limitations in the instant claims, as described above.

***Additional Prior Art***

While not being used in the prior art rejection, US 2004/0248144 (Mir) is being put on the record which includes a plurality of nucleic acid molecules being attached to a solid substrate (0123, 0126), using time-gated detection and a temporal profile (0252, 0235) with optical detection and mapping (0236, 0469, 0682), and sequencing of linearised DNA (0425-0439).

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. If you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, please call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

May 26, 2009

/Carolyn Smith/
Primary Examiner
AU 1631